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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/325,602 06/03/99 GALDES

A BIV-069.02

EXAMINER

025181 HM22/0213  
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ART UNIT

PAPER NUMBER

1653  
DATE MAILED:

02/13/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/325,602

Applicant(s)  
Galdes et al

Examiner  
F. T. Moezie

Group Art Unit  
1653



☒ Responsive to communication(s) filed on Aug 10, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-21 is/are pending in the application.

Of the above, claim(s) 5-10 and 12-21 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-4 and 11 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-21 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### **STATUS OF CLAIMS**

Claims 1-4 and 11 are pending prosecution in this Office action.

Claims 1-21 have originally been filed. Claims 1-8, 17, 20 and 21 are independent claims and claims 9-16, 18 and 19 are dependent claims.

In response to the Restriction Requirement, Office action mailed 7/31/00 applicant elected Group I invention, claims drawn to a method for promoting survival and /or functional performance of neuronal cells susceptible to excitotoxicity comprising contacting the cells with an amount of lipophilic modified hedgehog polypeptide, with traverse.

In response to the Species Election Requirement, applicant elected modified peptide specie of Example 7. However, *Example 7 does not disclose which particular hedgehog polypeptide (designated SEQ ID) was used in making the modified form thereof.*

Claim 11, drawn to a modified polypeptide is examined in this Office action to complete the elected invention. However, *claim 11 is objected to as it depends from non-elected invention.*

### **SEQUENCE LISTING REQUIREMENT IS INCOMPLETE**

The Sequence Listing submitted by applicant has been approved and entered.

However, the compliance with the requirement is incomplete for the reasons cited in the attached sheets.

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The format of the specification is not in accordance with the USPTO suggested format.

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

### **Arrangement of the Specification**

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- © Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
  - 1. Field of the Invention.
  - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (I) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

The References cited at pages 78-82 have not been considered by PTO. For consideration of the cited references by PTO, applicant would have to submit a proper IDS and a Form PTO-1449, listing all of the references therein together with a copy of each reference cited in the Form.

### **REJECTION - 35 USC 112, SECOND PARAGRAPHS**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims are indefinite and incomplete as to which parameters are being followed and what is the test environment, i.e., how the method(s) are monitored or how the course or the progress of is followed.

The claims are indefinite as to whether an in-vitro or an ex-vivo method is being claimed.

**REJECTION - 35 USC 103 (a)**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

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made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ingham et al in US Patent Nos. 5,844,079 and/or 5,789,543 in view of Pepinsky et al, in The Journal of Biological Chemistry, Vol. 273, no. 29, pp 14037-15045, 1998.

The primary references teach that the use of hedgehog polypeptide for regulating “neuronal differentiation during development of the nervous system and also presumably in the adult state indicate that certain of the hedgehog proteins can be reasonably expected to facilitate control of adult neurons with regard to maintenance, functional performance , and aging of the normal cells --- prevention of degradation and premature death ---” column 46 first paragraph of ‘079. See the entire documents, especially columns 43-49 of ‘079.

However, this reference does not disclose the use of a lipophilic modified polypeptide.

The secondary reference teaches: “The lipid-tethered forms of hedgehog showed about a 30 fold increase in potency --” Abstract. See, the entire document.

One of ordinary skill in the art at the time the invention was made would have been motivated to make and use a lipophilic modified form of hedgehog polypeptide and *expect* to obtain a greater potency in a method of use for the derivatized polypeptide.

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## RESPONSE TO APPLICANT

Applicant's remarks filed 18 August 2000, paper no. 8, regarding the traversal of the Restriction-Requirements have been fully considered and found persuasive in-part.

Claim 11 is now examined along with the elected invention.:

Remarks regarding the examination of claims drawn to *in-vitro* methods do not impose undue burden of search on the examiner regarding the examination of the *in-vivo* methods have been considered. However, it is clear that various and different factors and/or parameters must be considered in each category of invention. The *protocol*, the *objectives*, the *hosts* and the *environment* for the methods are entirely different in each invention. Furthermore, the searches are not coextensive as has been shown earlier. It would be an undue burden to examine all of the inventions in one application. Hence, the Restriction Requirement is found proper and maintained.

Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508.

*F.T. Moezie*

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